K023680

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510(k) Summary of Safety and Effectiveness
BioBuck™ Cement Restrictor

NOV 19 2002

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	October 31, 2002
Contact Person:	David Henley Senior Clinical/Regulatory Affairs Specialist Tel: (901) 399-6487 Fax: (901) 398-5146
Proprietary Name:	**BioBuck™ Cement Restrictor**
Common Name:	Cement Restrictor
Classification Name and Reference:	Cement Obturator
Device Product Code and Panel Code:	Orthopedics/87/LZN
Predicate Devices:	Buck™ Cement Restrictor (K791125) Shuttle Stop® Cement Restrictor (K000587) SynPlug™ Cement Restrictor (K010840)

Device Description:
The BioBuck™ Cement Restrictor is a bioabsorbable version and modification of the Buck™ Cement Restrictor that was cleared for marketing by FDA on 27 June 1979 (K791125). The material for the BioBuck device is PolyActive®, a biocompatible copolyether. PolyActive is currently used to manufacture other cement restrictor devices (Shuttle Stop®, K000587; SynPlug™, K010840).

Intended Use:
The BioBuck Cement Restrictor is a bullet-shaped plug with stabilizing and sealing rings intended for intramedullary occlusion during cemented hip and shoulder arthroplasty.

Technological Characteristics:
The principles of operation for the BioBuck Cement Restrictor are identical to the Buck Cement Restrictor, as well as the Shuttle Stop and SynPlug. All are cement plugs that are inserted in the intramedullary canal during implantation of a joint prosthesis to prevent the migration of bone cement. The design and material of the BioBuck device has the same technological characteristics as one or more of the predicate devices.

Substantial Equivalence Information:
The intended use of the BioBuck Cement Restrictor is identical to the predicate devices. The BioBuck device shape and design are very similar to the Buck predicate device, and the BioBuck device is manufactured from the identical material as the Shuttle Stop and SynPlug predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Smith & Nephew Incorporated
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

NOV 1 9 2002

Re: K023680
Trade Name: BioBuck™ Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Cement Obturator
Regulatory Class: II
Product Code: LZN
Dated: October 31, 2002
Received: November 1, 2002

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

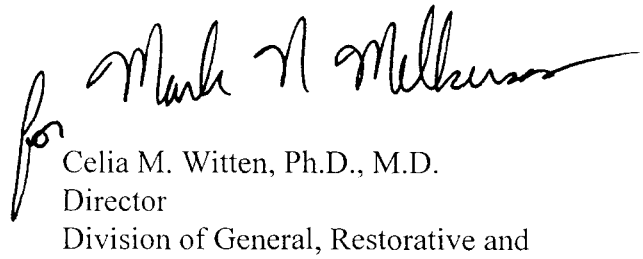
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

BioBuck™ Cement Restrictor

510(k) Number (if known): K023680

Device Name: **BioBuck™ Cement Restrictor**

Indications for Use:

The BioBuck™ Cement Restrictor is a bullet-shaped plug with stabilizing and sealing rings intended for intramedullary occlusion during cemented hip and shoulder arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023680

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The Counter Use _____ (Optional Format 1-2-96)